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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,769	09/10/2003	Thomas J. Wood	IMED-0010-US	4079
40575	7590	12/17/2004	EXAMINER	
KCO LAW P.L.L.C. /DBA KEADY, OLDS & MAIER, PLLC 128 NORTH PITT STREET, 2ND FLOOR ALEXANDRIA, VA 22314			MICHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/658,769	WOOD ET AL. <i>U</i>	
	<b>Examiner</b>	<b>Art Unit</b>	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1- 31 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 and 29 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23,28,30 and 31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 September 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/10/03;12/03/03</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Election/Restrictions***

Examiner Mitchell contacted Mr. Maier on 12/02/04 regarding lack of unity in PCT/US04/29459, at which time Mr. Maier elected group I, claims 1-23, 28, 30, and 31, drawn to a ventilation interface, with traverse (which election/restriction requirement sent to applicant). Claims 24-27 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1, 2, 4-23, and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-23 of copending Application No. 10/876,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of claim 1 of the instant application can be found in claims 1 and 2 of application'480. The instant application claim 1 is more specific than application**

'480 claim 1. Therefore, claim 1 of the instant application "anticipates" the broader claim 1 of application '480. **With respect to claim 2 of the instant application,** the limitations can be found in claim 1 of the application '480. With respect to claim 4 of the instant application, the limitations can be found in claim 4 of application '480. With respect to claim 5 of the instant application, the limitations can be found in claim 5 of application '480. With respect to claim 6 of the instant application, the limitations can be found in claim 6 of application '480. With respect to claim 7 of the instant application, the limitations can be found in claim 7 of application '480. With respect to claim 8 of the instant application, the limitations can be found in claim 8 of application '480. With respect to claim 9 of the instant application, the limitations can be found in claim 9 of application '480. With respect to claim 10 of the instant application, the limitations can be found in claim 10 of application '480. With respect to claim 11 of the instant application, the limitations can be found in claim 11 of application '480. With respect to claim 12 of the instant application, the limitations can be found in claim 12 of application '480. With respect to claim 13 of the instant application, the limitations can be found in claim 13 of application '480. With respect to claim 14 of the instant application, the limitations can be found in claim 14 of application '480. With respect to claim 15 of the instant application, the limitations can be found in claim 15 of application '480. With respect to claim 16 of the instant application, the limitations can be found in claim 16 of application '480. With respect to claim 17 of the instant application, the limitations can be found in claim 17 of application '480. With respect to claim 18 of the instant application, the limitations can be found in claim 18 of application '480. With respect to

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claim 19 of the instant application, the limitations can be found in claim 19 of application '480. With respect to claim 20 of the instant application, the limitations can be found in claim 20 of application '480. With respect to claim 21 of the instant application, the limitations can be found in claim 20 of application '480. With respect to claim 21 of the instant application, the limitations can be found in claim 21 of application '480. With respect to claim 22 of the instant application, the limitations can be found in claim 22 of application '480. With respect to claim 23 of the instant application, the limitations can be found in claim 23 of application '480. With respect to claim 30 of the instant application, the limitations can be found in claims 1 and 2 of application '480.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

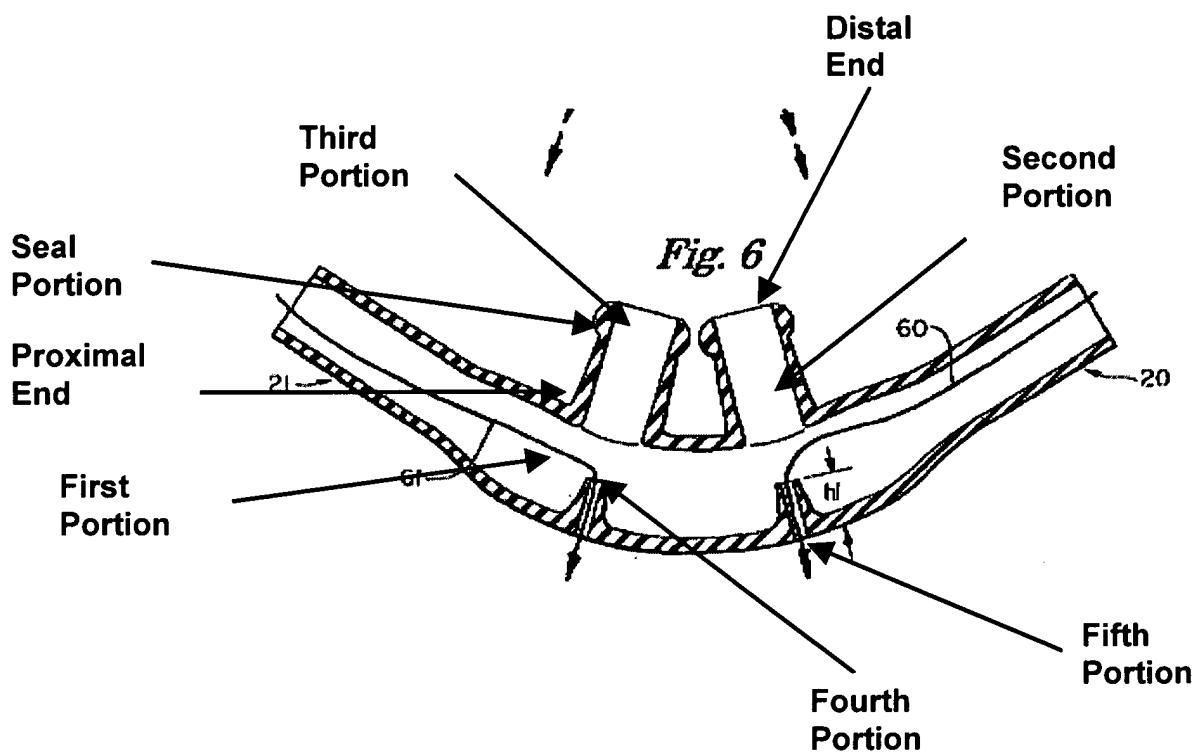
A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 4, 5, 14-18, 20-23, 28, 30, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Strickland et.al. (6,679,265).**

Strickland in a ventilation interface (10) discloses:

- a cannula (Figs. 3-7)
- with at least one nasal insert (12, 13) and at least one exhaust port (16, 17);  
the cannula forming a first portion of an input gas flow passage (see illustration of Fig. 4 below) to supply the ventilation gas to the user;
- the nasal insert being adapted to be inserted into a first naris of the nares of the user (Fig. 1),
- the nasal insert forming second and third portions of the input gas flow passage from the nasal cannula to a distal end of the nasal inset; and (see illustration of Fig. 6 below); and
- a seal portion (see illustration of Fig. 6 below) adapted to engage at least a portion of the nares, the seal portion being provided on the distal end of the at least one nasal insert;
- wherein the first, second, the third portions of the input gas flow passage are disposed at an obtuse angle to one another (Figs. 2-7).



With respect to claim 4, Strickland discloses wherein a proximal end of the nasal insert forms a second portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7).

With respect to claim 5, Strickland discloses wherein a distal end of the nasal insert forms a third portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7).

With respect to claim 14, Strickland discloses a gas output (16, 17) forming a portion of an output gas flow passage from the nasal insert to an exterior of the ventilation interface to channel a gas expired by the user.

With respect to claim 15, Strickland discloses wherein the second portion of the input gas flow passage formed by the nasal insert is about parallel with the portion of the output gas flow passage (Figs. 2-7).

With respect to claim 16, Strickland discloses wherein the second portion of the input gas flow passage and the portion of the output gas flow passage are configured to provide laminar flow there between (Figs. 2-7).

With respect to claim 17, Strickland discloses wherein a distal end of the gas output forms a first portion of the output gas flow passage having a substantially circular cross section (Figs. 2-7).

With respect to claim 18, Strickland discloses wherein a portion of the gas output proximal the cannula forms a second portion of the output gas flow passage having a substantially circular cross section.

With respect to claim 20, Strickland discloses wherein at least one of the nasal insert and the seal portion is sufficiently flexible to be expanded by a positive pressure provided by the ventilation gas (Col. 2, lines 41-67).

With respect to claim 21, Strickland discloses wherein at least one of the nasal insert and the seal portion forms a seal with the nares of the user by at least one of deformation of at least one of the nasal insert, the nares of the user, the seal portion or a headgear (Figs. 1-7; Col. 2, lines 41-67).

With respect to claim 22, Strickland discloses wherein at least one of the nasal inset and the seal portion forms a seal with the nares of the user by friction (Col. 1, lines 60-67 and Col. 2, lines 41-67).

With respect to claim 23, Strickland discloses wherein at least one of the nasal inserts and the seal portion form a seal with at least one naris of the user by a resiliency of at least one of said seal portion and said nares of the user and a headgear (Figs. 1-7 and Col. 2, lines 41-67).

With respect to claim 28, note rejection of claim 1 above.

With respect to claim 30, Strickland discloses a feed tube (20) and a y-connector (22) and headgear (18).

With respect to claim 31, Strickland discloses wherein the seal portion is configured to receive a skirt to prevent leakage (Figs. 2-7).

#### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.**

**Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).**

**Claims 2, 3, 6-13, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland et.al. (6,679,265).**

With respect to claim 2, Strickland does not disclose the specific obtuse angle being between 110° and about 170°. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the obtuse angle between 110° and about 170°, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, also because no user is alike it would be obvious based on the intended user that in order to receive the appropriate ventilation the obtuse angle would be different.

With respect to claims 3, 6, 10, 12, 13, and 19, note rejection of claim 2 above.

With respect to claim 7, Strickland discloses wherein the seal portion forms a third portion of the input gas flow passage having a substantially oval cross section (Figs. 2-7 and not illustration of Fig. 6 above).

With respect to claim 8, Strickland discloses wherein the distal end of the nasal insert includes a first exterior portion having a substantially oval cross section (Figs. 2-7).

With respect to claim 9, Strickland discloses wherein the portion of the nasal insert proximal the cannula includes a second exterior portion having a substantially oval cross section (Figs. 2-7).

With respect to claim 11, Strickland discloses wherein the seal portion includes a third exterior portion having at least one of substantially oval cross section or a round cross section (Figs. 2-7).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show ventilation interfaces: 5,975,077; 5,477,8524,782,832; 4,156,426; 1,818,028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Teena Mitchell*  
Teena Mitchell  
Examiner  
Art Unit 3743  
December 2, 2004